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Sent: 4/9/2019 8:49:23 PM

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Subject: OPPT/OPP/OCSPP Clips 4/9

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OPPT/OPP/OCSPP Clips

April 9, 2019

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Highlights

Bloomberg Environment

States Brace for Battle With EPA Over Pesticide Label Rules

https://news.bloombergenvironment.com/environment-and-energy/states-brace-for-battle-with-epa-over-pesticide-label-rules

Adam Allington

Posted: 10:53am, April 9, 2019

- 'Special local need' provisions allow states to restrict pesticides
- State regulators concerned EPA is moving to water down authority

State pesticide regulators are concerned the Environmental Protection Agency is angling to reduce their ability to impose additional restrictions on pesticides in their states.

The issue was front and center during a committee meeting of the Association of American Pesticide Control Officials (AAPCO) on April 8.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) gives states the power to set so-called "local need requirements" for pesticides, including adding rules besides those printed on the EPA-approved federal labels.

In recent years, states have used this provision, known as 24(c), to impose additional restrictions on the use of dicamba herbicides, which can drift and damage off-target crops—including some 3.6 million acres of soybeans across the Midwest in 2017, according to thousands of reports.

But the <u>EPA announced</u> March 19 that it is re-evaluating its approach to such requests and "the circumstances under which it will exercise its authority to disapprove those requests."

While states have the right to regulate pesticides by passing laws in their state, EPA highlighted the growing use of 24(c) to "implement more restrictive cut-off dates, or to add training and certification requirements, or to restrict the use directions by limiting the number of treatments permitted by the federal label."

The EPA said it would take public comment on any potential new approaches, and any changes wouldn't affect this year's growing season.

The agency said it currently receives about 300 such requests a year.

Letters to Wheeler

In addition to changing the pesticide labels, FIFRA also gives states the right to pass laws to regulate the sale or use of any federally registered pesticide.

But state regulators say the 24(c) provision allows them to address local issues more quickly, and with better nuance, than going through the legislature.

"It could take several years for many of these states to go through the rulemaking process," AAPCO President Rose Kachadoorian told fellow regulators at the April 8 meeting, causing unacceptable damage to crops and plants in the meantime.

"States are constantly collecting new data," she said, "and that's not the type of thing that you go to rulemaking with, when it's kind of this moving target as far as what cutoff date is going to work, what kind of training should you have, what kind of nozzle should you have."

AAPCO sent <u>a letter</u> on April 4 to EPA Administrator Andrew Wheeler raising these concerns. Using these requests "allows State Lead Agencies to be nimble, timely, practical and appropriately responsive," AAPCO said.

The letter was followed by a similar <u>statement</u> on April 5 from the National Association of State Departments of Agriculture (NASDA).

"We are concerned that a different interpretation could significantly impact the way states meet their local needs," wrote Barbara Glenn, CEO of NASDA.

When asked to respond to state regulators' concerns, an EPA spokesman declined to address specifics.

"We look forward to a robust public dialogue on this matter," he said.

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The Washington Post

Why both Major political parties have failed to curb dangerous pesticides

The Washington Post: Why both Major political parties have failed to curb dangerous pesticides

Elena Conis

Posted: 6:00am, April 9, 2019

The news that David Bernhardt, President Trump's Interior Secretary nominee, <u>blocked a federal report</u> on the risks certain pesticides pose to hundreds of endangered species has enraged scientists and environmental groups. "It is clear Mr. Bernhardt will always put the profits of his special-interest allies above the well-being of this nation's most imperiled animals and plants," said a coalition of 31 environmental and health-advocacy groups in a statement opposing Bernhardt's nomination.

But as infuriating as the Trump administration's favoritism toward the pesticide industry may be, it's actually nothing new. Since the dawn of the modern pesticide era during World War II, federal regulators in administrations from both major parties have adopted lax, pro-industry standards that have allowed potentially dangerous pesticides to remain legal.

World War II led to an explosion of synthetic pesticides that were cheap, easily manufactured and highly profitable for chemical companies, which raked in \$40 million in pesticide sales per year at the war's start and \$260 million over a decade later. Some of the new pesticides were astonishingly powerful: A single drop of Tepp could kill a mouse instantly. Others seemed incredibly safe. A naked man could sit with his back against the DDT-coated wall of a heated steel chamber for four days and emerge, allegedly, with no serious lasting effects. (We know this because one scientist found some "volunteers" to do just that.)

The power and number of the new pesticides called for a new federal law to regulate their use. The old law, dating to 1910, required little of pesticide makers. They simply had to label their products accurately, and it had been laxly enforced by the federal Bureau of Chemistry. The result was that all too often, unwitting shoppers took home apples,

asparagus, cabbage, pears, spinach, broccoli, celery and more with levels of arsenic and lead that could — and did — sicken and kill.

The postwar pesticide law drafted in 1947 was intended to halt such tragedies as it guided farmers through the landscape of new pesticides. But industry representatives played a crucial role in drafting the legislation, and it once again did far too little to protect the public. The new law required pesticide labels to include ingredients and directions, and information about antidotes in the case of serious "poisons," as pesticides were then called. It also required that pesticides resembling salt, sugar or flour be dyed another color, "to lessen the chance of housewives putting bug instead of baking powder into their biscuits," as the Associated Press wryly put it.

But the law elided a crucial question: What, exactly, constituted a poison? It depended on what kind of scientist you asked.

For scientists with the Public Health Service, poisons were chemicals that caused immediate harm, which you could document by observing men who worked with chemicals in factories and fields. Food and Drug Administration scientists, however, took a longer view. They advocated pre-market studies in lab animals to observe the full effects of a chemical over a lifetime or generation. When FDA scientists fed DDT to dogs, for instance, they were troubled to see evidence of neurological problems, liver damage and startlingly high levels of the chemical in puppies, who got it from breast milk. PHS scientists, meanwhile, examined DDT "spray men" who ended each work day drenched in DDT, and they seemed fine.

Whose science to rely on? The USDA, now in charge of pesticide oversight, chose the latter, which suited pesticide makers just fine.

With few market restrictions in place, the companies ramped up production. Between 1945 and 1950, U.S. manufacturers tripled the amount of pesticides produced. By 1952, the USDA had more than 20,000 new pesticide products to keep track of. All the while, cancer rates climbed and pesticides came under suspicion.

Highly publicized hearings in the 1950s, spearheaded by New York Rep. James Delaney, led to improvements, including an amendment to the federal Food, Drug and Cosmetic Act preventing USDA from registering any pesticides until the FDA set a "safe" residue level. As environmental scientist John Perkins pointed out decades ago, though, that was still a win for the pesticide industry, as it "legitimized" pesticide use by establishing "legal" doses.

President Richard M. Nixon's effort to overhaul federal pesticide law in 1971 produced <u>more meaningful change</u>. That law required manufacturers to submit health and safety testing data for any pesticide they wanted to register, and it granted the newly established Environmental Protection Agency authority to require additional data.

This should have made a big difference. But by the end of the 1970s, the EPA's pesticide office was drowning in a backlog of registration requests and, unable to keep up, chose to register pesticides whose applications included incomplete, unreliable and obsolete data.

This led to the creation of "conditional" registration: After 1978, companies could register new products without submitting all of the required safety and testing data. More than 16,000 pesticides have been registered for use in the United States; more than two-thirds were initially registered conditionally. Some, according to a Government Accountability Office report, have been conditionally registered for more than 20 years. One legal analysis declared this a long-standing "loophole" in federal pesticide law, one that allowed companies to circumvent the legal requirement to prove a product safe for health and the environment before selling it to the public.

One of those <u>conditionally registered compounds</u> was glyphosate, first brought to market in the 1970s and back in the headlines recently after a jury <u>awarded</u> \$80 million in damages to a Northern California man who claimed the Monsanto weedkiller Roundup caused his Non-Hodgkin Lymphoma. It's the second major jury decision against the pesticide in less than a year, and more cases are pending.

Conditional registration is not the only reason glyphosate has remained on the market. EPA scientists classified it as a carcinogen back in 1985 but <u>reversed course</u> after six years of correspondence with Monsanto executives. In the decades that followed, the company commissioned its own science from its preferred scientists and asked federal

regulators to base decisions on that science. In one instance, the EPA ceded to industry requests to remove a certain scientist from a glyphosate safety review panel.

In another, an EPA scientist promised Monsanto it would block a planned glyphosate safety review. The president whose EPA made this promise? Barack Obama.

This is our system for ensuring that pesticides are safe. They are innocent and on the market until proven guilty. Close relationships between industry and our regulatory agencies help keep them there. By the time enough independent science has produced evidence of harm, it's far too late to reverse the damage done.

It's no small irony that one of the pesticides in the report blocked by Bernhardt, malathion, was called out by Rachel Carson in "Silent Spring" in 1962. "The alleged 'safety' of malathion rests on precarious ground," she wrote. But the real problem was that, "as often happens — this was not discovered until the chemical had been in use for several years." Lawmakers and regulators must adopt a harder line toward pesticides. This is not a Democratic problem or a Republican problem. It's a long-standing American problem — one that risks the safety of our environment, our food supply and most importantly, our health.

Bee-Safe Pesticide

PR Newswire

The Frist Bee Safe Pesticide Will Have the Market Buzzing This Spring

PR Newswire: The Frist Bee Safe Pesticide Will Have the Market Buzzing This Spring

Organic Laberatories, INC. Posted: 5:00pm, April 8, 2019

FORT PIERCE, Fla., April 8, 2019 /PRNewswire/ -- Organic Laboratories, Inc., a leading producer of organic and earth-friendly pesticides and fertilizers, is the first to market a bee safe pesticide. Most of humanity is well-aware of the vital role bees play in pollinating flowering plants. Three-fourths of the world's flowering plants and approximately 35 percent of the world's food crops depend on animal pollinators to reproduce.

A steady decline in the bee population has been attributed to colony collapse disorder, caused in part by certain neonicotinoids that are used as pesticides. In order to protect the honey bee, the European Union has banned the use of those neonicotinoids outdoors and the U.S. Environmental Protection Agency has restricted its use while bees are present.

These recent changes have been the driving force for agricultural producers, nurseries and home gardeners to seek a "bee friendly" alternative.

Recently, i2LResearch, a leading product testing center headquartered in the United Kingdom, evaluated the effects of Organocide® Bee Safe 3-in-1 Garden Spray on honey bees. In summary,

"A laboratory study followed EPA (2012) test guideline to assess acute contact toxicity of Organocide Bee Safe 3-in-1 Garden Spray (Sesame oil 5%) to honey bees (Apis mellifera). The goal of the definitive test was to determine the dose-response curve for honey bee mortality after a 48 h acute contact. The product was tested at 5 rates."

Overview of the honey bee mortality after 48 h acute contact with Organocide Bee Safe 3-in-1 Garden Spray. *Maximum application test rate applied at full concentration. **Label's application rate. (See link below.)

Table 1. https://cdn.newswire.com/files/x/9b/00/94f36b9f92dc4ef24c9a0e974453.png

Organocide* Bee Safe 3-in-1 Garden Spray is an insecticide, miticide and fungicide that has been used in organic gardening for more than 27 years. It has been proven effective in destroying all life stages of small soft-bodied insects (including aphids, fungus gnats, leaf rollers, psyllids, spider mites, scale and whiteflies) and controlling fungal diseases (like powdery and downy mildews). It is safe enough to use near aquatics and it won't harm beneficial insects like ladybugs, butterflies, or our precious pollinating bees. It is people, pet and planet safe! It is available for purchase at select Home Depot, Walmart and Independent Hardware and Nursery retailers.

Email: Info@YourPlantDoctor.com

Dicamba

Sussex Living

Dicamba users should check EPA website

https://www.sussexcountian.com/news/20190409/dicamba-users-should-check-epa-website

Shannon Marvel McNaught Posted: 3:00pm, April 9, 2019

Limitations protect endangered species

In order to protect endangered species, farmers using the pesticide dicamba should check a U.S. Environmental Protection Agency website before applying it to their crops.

Dicamba, also known as Xtendimax, FeXapan and Engenia, is a benzoic acid herbicide. It's produced by Bayer, formerly Monsanto.

According to Bayer, dicamba is the active ingredient in a variety of products commonly used to control broadleaf weeds. Dandelions, clover and common ragweed are all examples.

"Dicamba has been on the market for a long, long time," said Christopher Wade, state Department of Agricuture pesticides section administrator. "Recently, it was reformulated to be used over the top on soybeans, so it's kind of had a resurgence in the market."

Dicamba is extremely effective – so effective that it had the unintended effect of damaging other crops when it drifts. Bayer, in turn, created a dicamba formula for use with their own genetically modified, dicamba-tolerant cotton and soybeans.

However, not all farmers choose to use their modified plants. Dicamba can injure their crops and any other plants it drifts across.

"There have been issues in some states, like in the Midwest, with the product," Wade said. "But it's warmer there. We haven't had any problems (in Delaware)."

Regardless, all users are required to follow the directions on the label and, according to Wade, that's the number one thing they can do to prevent undesired effects.

"The label is the law in Delaware," he said. "If there's something on the label you don't understand, we're here to help."

Dicamba labels direct users to the <u>EPA's Bulletins Livel Two</u> to check for pesticide use limitation areas, which exist to protect endangered species. In Sussex County, there are limitation areas for the protection of seabeach amaranth, an endangered coastal plant species.

The Bulletins Live! Two system is updated monthly and pesticide applicators are urged to check it as often as possible.

Find the link and more information at de.gov/pesticides/.

Glyphosate

Beyond Pesticides

Ban Glyphosate, Adopt Organic

https://beyondpesticides.org/dailynewsblog/2019/04/ban-glyphosate-adopt-organic/

Staff

Posted: April 9, 2019

(Beyond Pesticides, April 9, 2019) It is time for all local and state governments and school districts to stop the use of glyphosate/Roundup. The last month has seen a level of activity that supports immediate action. A second jury came in with the verdict that the herbicide caused plaintiffs' non-Hodgkin's lymphoma (NHL) —this time handing the manufacturer, Monsanto/Bayer, a bill for \$80 million (\$5 million in compensatory damages and \$75 million in punitive damages).

Tell your Governor to act now to stop the use of glyphosate/Roundup.

Insurance companies are now backing away from Roundup. Harrell's is a company that sells chemical pesticides, synthetic fertilizers, and "adjuvants and colorants," among other products, primarily to golf courses, and to the horticulture-nursery, turf, and landscape sectors. The company announced on March 11 that it stopped selling products containing glyphosate as of March 1, 2019 because neither its current insurance company nor others the company consulted would underwrite coverage for the company for any glyphosate-related claims.

Harrell's CEO stated: "During our annual insurance renewal last month, we were surprised to learn that our insurance company was no longer willing to provide coverage for claims related to glyphosate due to the recent high-profile lawsuit and the many thousands of lawsuits since. We sought coverage from other companies but could not buy adequate coverage for the risk we would be incurring. So we had no choice other than to notify our Harrell's Team and customers that we would no longer offer products containing glyphosate."

The announcement stands in contrast to a Fox Business story shortly after the verdict in the Johnson v. Monsanto case. That article reported, "Top U.S. retailers such as Home Depot, Target, Walmart and Amazon are sticking by Monsanto's controversial weedkiller Roundup one week after a California jury awarded a school groundskeeper \$289

million for proving the spray caused him to develop non-Hodgkin's lymphoma." Indeed, insurer (and perhaps re-insurer) concern may well increase in light of the deluge of lawsuits glyphosate use has triggered.

Meanwhile scientific studies linking glyphosate to serious adverse effects still keep coming in. A recent study by Fabiana Manservisi, Corina Lesseur, et al., published in Environmental Health on March 12, shows glyphosate-based herbicides are associated with endocrine and reproductive effects. This is on top of the scientific findings by the World Health Organization that the chemical probably causes cancer. A meta-study in February 2018 concluded that there is a "compelling link between exposures to GBH [glyphosate-based herbicides] and increased risk of NHL." Still the U.S. Environmental Protection Agency fails to act.

On March 1, the City of Miami established a ban, which went into immediate effect, on the use of any glyphosate-based herbicides (including Roundup compounds) by the city and any of its contractors.

It is time to stop glyphosate use or risk continued exposure to the state's populations and adverse health effects, along with the financial exposure that the threat of litigation brings.

Beyond Pesticides and other organizations that have worked for many years to educate stakeholders and policy makers about the dangers of pesticides, stand ready to assist the state and communities in transforming pest management by eliminating a reliance on toxic pesticides and adopting organic management practices.

Tell your Governor to act now to stop the use of glyphosate/Roundup.

Letter to Your Governor:

It is time for all local and state governments and school districts to stop the use of glyphosate/Roundup. The last month has seen a level of activity that supports immediate action. A second jury came in with the verdict that the herbicide caused plaintiffs' non-Hodgkin's lymphoma (NHL) —this time handing the manufacturer, Monsanto/Bayer, a bill for \$80 million (\$5 million in compensatory damages and \$75 million in punitive damages).

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Concern has increased since a Fox Business story shortly after the verdict in the Johnson v. Monsanto case, which reported, "Top U.S. retailers such as Home Depot, Target, Walmart and Amazon are sticking by Monsanto's controversial weedkiller Roundup one week after a California jury awarded a school groundskeeper \$289 million for proving the spray caused him to develop non-Hodgkin's lymphoma." Indeed, insurer (and perhaps re-insurer) concern may well increase in light of the deluge of lawsuits glyphosate use has triggered.

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Thank you for your attention to this important matter.

Capital Press

Empowering Producers of Food and Fiber

Capital Press: Empowering Producers of Food and Fiber

Ben Scholz

Posted: 7:00pm, April 8, 2019

Too often, science and facts fall victim to fear mongering and emotion. Recently, we have seen an uptick in false narratives around wheat growers' use of the herbicide glyphosate. The reality is that glyphosate, the active ingredient in many herbicide brands, including Roundup herbicide, is one of the most effective tools to combat weeds prior to planting or after wheat is harvested.

While there are many claims about glyphosate, the tillage replacement tool has more than a 40-year history of safe use. Further, despite comments by ill-informed interest groups, farmers do not "douse" their crops with glyphosate just prior to harvest or in any application. Like all pesticides, glyphosate works best when used precisely and correctly, and it's against the law to use it in a manner that is contrary to the U.S. Environmental Protection Agency-approved label. Farmers participate in training on how to follow the requirements of EPA labels and don't want to use any more than they need, because the products are costly and take time to apply.

Glyphosate has been a breakthrough for agriculture, and this includes wheat production. Not only do glyphosate products control weeds, but they also help farmers farm the land sustainably. It is a safe and effective product, allowing farmers to manage their crops without bringing risk to themselves, their families, their workers and the environment.

As a matter of fact, the U.S. Department of Agriculture has deemed glyphosate to be more environmentally friendly than alternative tillage methods and cropping systems using higher-risk herbicide products. It has become a very effective

and useful tool for protecting soil erosion, fertility and water quality. It has led to an increase of growers incorporating no-till farming practices into their operations.

To be clear, no-till is an agricultural technique that does not disturb the soil and leaves the previous crop residue on the soil surface. This has been shown to increase the amount of water that infiltrates the soil, thereby reducing water runoff and soil erosion and sequestering carbon. The most powerful benefit of no-till is improvement in soil biological health, making soils more resilient and sustainable for continued crop production. Despite what you might read or hear, glyphosate only hurts the weeds.

Glyphosate and glyphosate-based herbicides are among the most rigorously studied products of their kind. Hundreds of studies have been submitted to the U.S. EPA, the European Food Safety Authority, and other regulatory agencies around the world as required with the registration process, and all have confirmed that this product is safe for use as labeled. As a result of these rigorous registration studies proving its safety, glyphosate is approved for use in more than 160 countries.

Recently, the herbicide received further corroboration of its safety, though this news doesn't always make the headlines. In 2018, the U.S. EPA convened its own panel to review glyphosate and concluded that "it is not likely to be carcinogenic in humans." Glyphosate, given its effectiveness and broad adaptation in production agriculture, is justifiably one of the most studied and closely monitored herbicides in the world.

The U.S. food supply is safe, and glyphosate is a critical component in keeping it that way. To meet the demands of a growing world population, farmers need access to all available technology and products that enable them to improve pest management and provide an abundant, safe, high-quality food supply. Only glyphosate provides farmers the unique combination of efficacy and environmental friendliness needed to tackle world hunger. The mechanical tillage that farmers would be required to implement without glyphosate would result in higher costs, environmental and soil degradation, and likely a less safe herbicide applied in the first place. Careening toward this result, as we are currently doing, should not be an option when so much is at stake.

Ben Scholz is president of the National Association of Wheat Growers and a Lavon, Texas, wheat farmer.

The Wall Street Journal

Roundup, the World's Best-Selling Weedkiller, Faces a Legal Reckoning

https://www.wsj.com/articles/roundup-the-weedkiller-that-changed-farming-faces-a-reckoning-11554735900

Jacob Bunge, Ruth Bender Posted: 11:59pm, April 8, 2019

verdict.

For years, scientists at Monsanto Co. worked closely with outside researchers on studies that concluded its Roundup weedkiller was safe.

That collaboration is now one of the biggest liabilities for the world's most widely used herbicide and its new

owner, <u>Bayer</u> AG <u>BAYRY -0.64%</u>, which faces mounting lawsuits alleging a cancer link to Roundup.

Plaintiffs' attorneys are putting Monsanto's ties to the scientific community at the center of a series of high-stakes suits against Bayer. Since the German company <u>acquired Monsanto last June</u>, two juries in California have sided with plaintiffs who have lymphoma and blamed the herbicide for their disease. Bayer's shares have fallen roughly 35% since the first

In both cases, plaintiffs' attorneys argued that Monsanto's influence on outside studies of Roundup's active ingredient tainted the safety research. The attorneys obtained certain Monsanto emails showing outside scientists asking the company's scientists to review their manuscript drafts, and Monsanto scientists suggesting edits.

Gary Kitahata, a member of a jury that <u>ordered Bayer to pay \$289.2 million</u> to a former California groundskeeper with non-Hodgkin lymphoma last August, said Monsanto's interaction with outside researchers played an important role in jurors' deliberations. He recalled being struck by emails allegedly dealing with "things like ghostwriting, influencing scientific studies that were done." A judge later reduced <u>the award, which Bayer is appealing, to \$78.5 million</u>.

Last month, a federal jury in San Francisco <u>awarded \$80.3 million</u> to another man with non-Hodgkin lymphoma who had used Roundup, a verdict Bayer also plans to challenge. Another trial is under way in Oakland, involving two more of the 11,200 U.S. farmers, landscapers and others who have filed suit, threatening product-liability costs at Bayer for years to come.

Bayer said hundreds of studies and regulatory decisions across the globe show the active ingredient in Roundup, called glyphosate, is safe and isn't carcinogenic. Regulators in the U.S. and abroad have continued to approve its use, in some cases after having gone back and taken another look at research criticized by plaintiffs' attorneys.

"Plaintiff lawyers have cherry-picked isolated emails out of more than 20 million pages of documents produced during discovery to attempt to distort the scientific record and Monsanto's role," Bayer said. A spokesman said the documents at issue relate only to secondary reviews of past research, not to the original science. He added that the outside scientists have stood by their conclusions.

In the U.S., Roundup has become almost as fundamental to farming as tractors. American farmers <u>use it or other</u> <u>glyphosate-based herbicides on the vast majority of their corn, soybean and cotton acres, making it a factor in American agriculture's steadily rising productivity.</u>

Monsanto developed the chemical decades ago and later introduced crops genetically engineered to survive being sprayed with it, driving what is now a more than \$9 billion seed business for Bayer. Annual sales of glyphosate herbicides, including by competitors, total around \$5 billion, according to Sanford C. Bernstein.

Despite their regulatory acceptance, the herbicides have faced growing resistance, especially since a 2015 decision by the International Agency for Research on Cancer, a World Health Organization unit, <u>classifying glyphosate as likely having the potential to cause cancer in humans</u>. In January, a <u>French court banned a Roundup product with the ingredient</u>, even though it had a European Union seal of approval.

Legal Challenge

<u>Costco Wholesale</u> Corp. recently pulled Roundup herbicides from its stores, according to an executive of the retailer. Certain cities in California, Florida, Minnesota and elsewhere have forbidden glyphosate weedkillers on municipal property. Other farm-state lawmakers have defended the herbicides.

The attack on Monsanto's role in research that deems Roundup safe is led by Baum Hedlund Aristei Goldman PC, a law firm representing more than 1,400 plaintiffs. It has selectively released hundreds of company emails obtained through legal discovery and put many of them on its website.

"These documents provide evidence that Monsanto's been actively engaged in manipulating the science regarding glyphosate's carcinogenicity," said Michael Baum, the firm's managing partner.

One document cited by plaintiffs' attorneys is a 2000 email that Monsanto's Hugh Grant, later the company's chief executive, sent following the publication of a paper upholding Roundup's safety. "This is very good work, well done to the team," he wrote to Monsanto scientists.

They weren't the paper's authors. Outside scientists were. An acknowledgements section cited Monsanto researchers as having provided scientific support. They had reviewed the text and data, according to <u>internal Monsanto</u> communications.

Mr. Grant, who retired after Bayer acquired Monsanto for \$63 billion, declined to comment, Bayer said.

Bayer said collaboration with outside scientists is important for purposes such as testing safety and efficacy, and it provides properly disclosed compensation for outside scientists' work, adding that this pay isn't given to influence their scientific opinions.

Helmut Greim, a retired toxicology professor at the Technical University of Munich who has worked with Monsanto, said, "There is this perception that industry is evil and that whoever is involved with them is at least equally evil."

"If the industry asks a scientist to help," he added, "I see it as my duty to do so. But one shouldn't let oneself be influenced."

Some regulators say when a research paper discloses industry funding, they take into account the possibility of corporate influence on the findings. "We generally are a bit more suspicious," said Bjorn Hansen, executive director of the European Chemicals Agency.

The chemicals agency and the European Food Safety Authority both re-examined glyphosate studies questioned by plaintiffs' attorneys and let stand their approvals. The agencies said they look at the raw data in research, so that the kind of study the attorneys question—a review of past research—generally doesn't carry much weight.

Health Canada also recently took a second look at studies on which it had based its approval of glyphosate herbicides, after critics raised concerns about Monsanto's role in research. The Canadian agency assigned a separate group of its scientists to go over the studies. Their review didn't change its conclusion.

The U.S. Environmental Protection Agency is currently doing a periodic review of the glyphosate science, ahead of a decision expected soon on extending glyphosate's longstanding U.S. approval. The EPA's most recent review of glyphosate's potential human risk, in late 2017, continued to find the chemical unlikely to cause cancer in humans.

A spokesman for the EPA said it has practices in place to "ensure that [company]-developed data represent sound science."

Scientific research in industry and academia has become more entwined over the years, scientists say, as corporations have become a more important funding source. Since 2007, U.S. federal government spending on basic scientific research has plateaued at around \$38 billion annually, according to data from the National Science Foundation.

Corporate funding has roughly doubled in that time, to about \$27 billion.

Companies or industry groups that finance research often include in contracts a right to review early versions of studies, said academics, who added that government-funded entities may attach a similar requirement.

For researchers with fewer options allowing them to be fully independent, "to some extent, they have to play by the industry's rules," said Sharon Batt, an adjunct bioethics professor at Dalhousie University in Halifax, Nova Scotia.

A 1998 review of 70 articles on the safety of a hypertension medication found that authors who produced conclusions supporting its use were nearly twice as likely as neutral or critical authors to have financial relationships with manufacturers. The review, on drugs called calcium-channel antagonists, was published in the New England Journal of Medicine.

A 2003 analysis of studies on industry-sponsored biomedical research found corporate-funded studies were more than 3½ times as likely to show results favorable to companies as were studies with no industry funding. The analysis appeared in the Journal of the American Medical Association.

In 2002, researcher Susan Monheit was writing an article on glyphosate herbicides used against aquatic weeds and sent a draft to a Monsanto regulatory-affairs official for fact checking. The official forwarded it to Monsanto toxicologist

Donna Farmer, according to emails that the Baum Hedlund law firm obtained in discovery and that The Wall Street Journal reviewed.

Ms. Farmer told the official the paper needed organizational work. "During one editing I had basically re-written the thing—then decided that was not a good thing to do so I tried to just correct the inaccuracies," she wrote to the regulatory-affairs official, Martin Lemon.

In an interview, Ms. Monheit, who worked at the California Department of Food and Agriculture, said Mr. Lemon passed along Monsanto's suggestions by telephone and she followed some of them, such as deleting references to old information. "I certainly didn't want to use data that was out of date," she said, but "I was wary of having Monsanto influence the article."

When her article was published in a weed-control newsletter called Noxious Times, concluding the chemical posed minimal risk to wildlife, a note described it as the product of a review of previously published research and consultations with pesticide chemists and eco-toxicologists. The note didn't name Monsanto.

Bayer didn't make the employees available for interviews.

In the late 2000s, Monsanto financed a study done partly by Pamela Mink, then an assistant professor of epidemiology at Emory University, reviewing past research on glyphosate's safety. Shown a draft, Monsanto's Ms. Farmer suggested some edits, mostly to the introduction, and circulated the draft to fellow company scientists, according to documents produced in the litigation and reviewed by the Journal.

One of the Monsanto scientists, Daniel Goldstein, added his own suggestions. "There are a couple places where I read the sentences several times, and I just can't gather what the underlying message is," he emailed Ms. Farmer. The two suggested deleting redundant phrases, asked for math to be double-checked and corrected names.

When the paper was published in the journal Regulatory Toxicology and Pharmacology in June 2012, some of the critiqued passages didn't appear, while others were rephrased and expanded. Brian Stekloff, a lawyer representing Bayer, said in court last month that Ms. Farmer moved around words in the introduction and added context about Roundup products that outside scientists would not have had.

The final paper was significantly different from the draft but had the same conclusion, which was that the researchers had found no pattern showing glyphosate exposure caused cancer in humans.

Its authors were listed as Dr. Mink and three other researchers who, like her, were affiliated with science consultancy Exponent Inc. The paper said one of the authors had been a paid consultant to Monsanto. "Final decisions regarding the content of the manuscript were made solely by the four authors," it said.

Dr. Mink didn't respond to requests for comment.

Dr. Greim, the retired Munich toxicology professor, said Monsanto approached him in 2013 about helping it publish

some unpublished internal research it earlier submitted to regulatory bodies.

He said Monsanto officials sent him a draft of a report. "I told them, 'That's not how it's done, you need a lot more

information" to support the conclusions, Dr. Greim said. He said he went back and forth with company scientists for

months, asking them to add details such as the number of animals and organs studied, and changing the presentation of

the results, until he felt the paper was satisfactory.

Monsanto accepted all of his suggestions, Dr. Greim said, and "there were a lot of passages I ended up writing." He said

he was paid €3,000, or about \$3,400, for his work.

When the paper was published in Critical Reviews in Toxicology in 2015—finding no link between the Roundup

ingredient and cancer—Dr. Greim appeared as lead author. A "declaration of interest" section said that he had been

paid by Monsanto and that his three co-authors had connections to the glyphosate business, including one who was

employed by Monsanto.

In an internal Monsanto memo released by the Baum Hedlund law firm, a Monsanto scientist listed among his

accomplishments "ghost wrote cancer review paper Greim et al. (2015)."

Dr. Greim, who has sat on various German and EU scientific advisory committees, said he didn't care what was said

internally because that wasn't what happened.

Bayer attorney Mr. Stekloff, speaking generally, said in court last month that there were instances of "dumb emails" and

"bad language" among the many company documents produced in the case, but "the overall record demonstrates that

this was a company committed to testing and committed to science."

—Sara Randazzo and Sarah Nassauer contributed to this article.

PFAS

Bucks County Courier Times

Top Senate Dem visits Horsham to tout PFAS chemical bill

https://www.buckscountycouriertimes.com/news/20190408/top-senate-dem-visits-horsham-to-tout-pfas-chemical-

bill

Kyle Bagenstose

Posted: 5:04pm, April 8, 2019

Delaware Senator Tom Carper, the top Democrat on the Senate's Environment and Public Works Committee, joined Pennsylvania Senator Bob Casey in Horsham Monday morning to lay out a plan to force the EPA to declare PFAS chemicals hazardous substances under the Superfund law.

The Senate's top-ranking Democrat on the Environment and Public Works Committee, Tom Carper, of Delaware, joined Sen. Bob Casey, D-Scranton, in Horsham on Monday to tout what they said is a plan to force the federal government to do more about toxic firefighting chemicals in drinking water.

Per- and polyfluoroalkykl substances, or PFAS, have been the subject of much concern in Bucks and Montgomery Counties since they were discovered about five years ago in public water supplies in Warminster, Warrington and Horsham. They originated in firefighting foams used at a trio of former and current military bases on both sides of the county line.

But the chemicals remain mostly unregulated at the federal level, causing headaches for affected communities here and across the country, as well as a growing number of <u>state regulators</u> trying to force the military and other polluters to cleanup the chemicals and protect public health.

Enter Carper, whose <u>PFAS Action Act of 2019</u> stipulates that within one year of the bill's passage, the Environmental Protection Agency administrator, currently Andrew Wheeler, must designate PFAS as hazardous waste under the federal Superfund law.

Legal experts say doing so would enable regulators at all levels to more successfully demand cleanup activities and unlock funding sources. But the idea is tied up at the EPA, whose leaders have said for nearly a year they would move toward adding PFAS to the Superfund program, but have yet to fully detail a plan or timeline.

"It's time for the federal government to stop just deliberating, and take action," Casey said Monday in announcing he would cosponsor the bill. "One of the ways they could take action is get out of the way and let us pass Senator Carper's legislation."

According to Congress' <u>website</u>, Casey is the bill's 31st sponsor in the Senate. So far, 24 Democrats, one independent, and six Republicans have signed onto the bill. U.S. Sen. Pat Toomey, R-Allentown, is not currently a co-sponsor, but his office said he "appreciates" the efforts and will follow the "debate closely" if Carper's committee considers the bill.

"Senator Toomey has led multiple efforts to ensure that the EPA, CDC, and DOD are doing everything that is necessary to address the PFAS contamination in Bucks and Montgomery Counties," said press secretary Bill Jaffee, citing Toomey's support for health screenings and studies for residents and service members and request that the EPA visit affected communities in Pennsylvania, which occurred last summer.

A House version of the bill has 33 cosponsors: two Republicans and 31 Democrats. U.S. Reps. Brendan Boyle, D-2, of Philadelphia and Madeleine Dean, D-4, of Abington, are co-sponsors, while U.S. Rep. Brian Fitzpatrick, R-1, of Middletown, is currently not. His office said Monday that Fitzpatrick has been focused on the creation of a drinking water standard for the chemicals, and intends to become a co-sponsor of the House version of Carper's bill.

Before holding a joint press conference touting the bill at the Horsham Township Library on Monday morning, the senators met privately with a group of local municipal leaders and residents, as well as state Sen. Maria Collett, D-12, of Lower Gwynedd, and Todd Stephens, R-151, of Horsham.

Carper said it was during the meeting that he learned of, and warmed to, the idea of including the bill's language in military appropriations legislation that Congress takes up every other year.

Casey and colleagues previously used the legislation, called the National Defense Authorization Act, to appropriate \$10 million in annual funding for a nationwide PFAS health study. The must-pass legislation is often an avenue for lawmakers to attach funding for priorities they otherwise might not get through an increasingly gridlocked Congress.

"A light went off in my head," Carper said, adding it was a "good idea."

Carper said he was also inspired by speaking to local residents impacted by the chemicals. He said he intended to try and find affected people in states across the country to convince Senate colleagues in backing the effort.

"All politics is local," Carper said.

But waiting for the appropriations bill presents its own issues. Carper said the bill is typically passed at the end of each congressional session, meaning it wouldn't become law until the latter part of 2020. Given the one-year window for the EPA to take action, the deadline would likely be more than two years away.

Still, Hope Grosse and Joanne Stanton, local residents who formed the BuxMont Coalition for Safer Water around the issue, liked the idea that the legislation designated a specific deadline, which they said was lacking in other bills they'd seen.

"Sometimes bills get introduced, and then they say, 'Well we have to wait for the budget, we have to wait for this,'"
Stanton said. "At least, if it does get passed, it should be implemented within a year."

Carper's office later clarified he would support the bill as either standalone legislation or rolled into the military appropriations, whichever can be achieved more quickly.

The senators were also asked about how the bill would actually work to force the EPA to designate PFAS as hazardous substances. Casey responded that the bill would have "the force of law, making sure the designation is made."

"We shouldn't have to do this," Casey added. "If they need to be compelled ... that's what we'll do by statute."

During the private meeting, Stanton and Grosse said they also raised concerns over the <u>recent news</u> that the nationwide PFAS health study would not include analysis of whether the chemicals are tied to higher cancer rates. They said the senators were sympathetic to the issue.

"They did not know that cancer would not be included," Stanton said. "They didn't know the details of the study. They agreed that cancer is definitely something that is on the mind of residents, and that it shouldn't be discarded."

In an emailed statement, Casey said he was "concerned" about cancer being left out and would contact the U.S. Centers for Disease Control and Prevention.

"I plan to follow up with CDC to urge them to include this aspect after hearing the stories of members of these communities today," Casey said. "If CDC does not have sufficient resources to evaluate cancer risks in its multi-site study, I will work with my colleagues in Congress to ensure we provide adequate funding to study all relevant PFAS-related health effects."

Stanton said her organization will continue advocating for political efforts on PFAS, particularly for the health studies, but has moved toward taking its own actions due to past disappointments with government inaction.

"We're looking at other ways to help the community and other avenues to get health studies brought into the com